
To: MARIFRAN MATTSON
BRNG

From: JEANNIE DICLEMENTI, Chair
Social Science IRB

Date: 03/14/2019

Committee Action: Expedited Approval - Category(6) (7)

IRB Approval Date 03/12/2019

IRB Protocol # 1606017855

Study Title Sexual Health Education: What Students Really Want to Know

Expiration Date 03/11/2022

Subjects Approved: 200

The above-referenced protocol has been approved by the Purdue IRB. This approval permits the recruitment of subjects up to the number indicated on the application and the conduct of the research as it is approved.

The IRB approved and dated consent, assent, and information form(s) for this protocol are in the Attachments section of this protocol in CoeusLite. Subjects who sign a consent form must be given a signed copy to take home with them. Information forms should not be signed.

Record Keeping: The PI is responsible for keeping all regulated documents, including IRB correspondence such as this letter, approved study documents, and signed consent forms for at least three (3) years following protocol closure for audit purposes. Documents regulated by HIPAA, such as Authorizations, must be maintained for six (6) years. If the PI leaves Purdue during this time, a copy of the regulatory file must be left with a designated records custodian, and the identity of this custodian must be communicated to the IRB.

Change of Institutions: If the PI leaves Purdue, the study must be closed or the PI must be replaced on the study through the Amendment process. If the PI wants to transfer the study to another institution, please contact the IRB to make arrangements for the transfer.

Changes to the approved protocol: A change to any aspect of this protocol must be approved by the IRB before it is implemented, except when necessary to eliminate apparent immediate hazards to the subject. In such situations, the IRB should be notified immediately. To request a change, submit an Amendment to the IRB through CoeusLite.

Continuing Review/Study Closure: No human subject research may be conducted without IRB approval. IRB approval for this study expires on the expiration date set out above. The study must be close or re-reviewed (aka continuing review) and approved by the IRB before the expiration date passes. Both Continuing Review and Closure may be requested through CoeusLite.

Unanticipated Problems/Adverse Events: Unanticipated problems involving risks to subjects or others, serious adverse events, and serious noncompliance with the approved protocol must be reported to the IRB immediately through CoeusLite. All other adverse events and minor protocol deviations should be reported at the time of Continuing Review.